REMARKS

In the most recently received (non-final) Official Action mailed January 25th, 2007, as extended through June 25th, 2007, the Patent Examiners of record have stated only a single rejection basis: Previously pending claims 6, 9 and 10 respectively are rejected under 35 USC 102(b) as being anticipated by the Ducharme *et al* .'740 patent [U.S. Patent No. 5,000,740]. In response, applicant has taken the following actions:

(i) Applicant has amended independent claims 9 and10 respectively; and

(ii) Applicant has retained the previously presented wording of dependent claim 6.

Accordingly, via the present claim amendments, as well as by the discussion presented hereinafter, applicant believes he has overcome and obviated the single basis for rejection stated by the Examiners in the most recently received (non-final) Official Action.

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I. The Examiners' Continuing Erroneous Views

A. The Examiners have once more rejected the definition of applicant's invention presented by independent claims 9 and 10 respectively, but now have employed a single and newly cited and applied reference (the Ducharme *et al* .'740 patent) as the basis for their rejection. The Examiners have stated their views and position at Pages 2-3 in the instant Official Action.

However, while the Examiners have presented what they believe to be a new and relevant prior art reference, the Examiners have nevertheless continued their earlier erroneous practices of review by wrongly concentrating on the conventionally known features shared in common by most intravenous catheters; by over-emphasizing the trivial and irrelevant; and by markedly distorting the meaning and value of the commonplace.

Despite the litany presented at pages 2-3 in the present Official Action, the reasons actually given by the Examiners for their instant rejection of the pending claims are seriously flawed. In particular, the Examiners' stated review neither properly recognizes nor gives appropriate value to what is the wording of claims 9 and 10 respectively; and the Examiners do not take into account the recited essential structural features actually recited by the definitions which separate and distinguish the present invention from the

prior art. For these reasons, applicant respectfully submits and maintains that the Examiners' stated evaluation and the conclusions drawn by the Examiners effectively continue to ignore the subject matter as a whole which constitutes applicant's claimed invention.

B. It is noteworthy that in the present instance, the Examiners' views as expressed at pages 2-3 of the Official Action, reveal the following kinds of errors: (a) The Examiners have wrongly inferred the presence of structural features and have erroneously attributed functional capabilities onto the innovation disclosed by the single cited and applied reference of record, but these structures and functions *do not in fact exist within and are not implied by the reference*; (b) the Examiners have improperly concentrated upon and wrongly emphasized the existence of merely incidental features and minor auxiliary structures which are present within the innovation disclosed by the single cited and applied reference, but which the reference itself recognizes as being peripheral and non-essential structures shared in common with previously known intravenous needle-catheter assemblies; and (c) the Examiners have again indulged in their unfortunate practice of pointing vaguely and elusively to certain prior art figures [such as Fig. 9B] in the cited and applied reference as embodying or showing certain structures and features, but where an objective review and close inspection of the figure

itself reveals that the figure is neither exemplary nor illustrative of any direct evidence or objective facts which pertain to applicant's claimed invention.

In consequence, applicant maintains that the Examiners' reasons and rationale stated in the instant Official Action are based on an inaccurate and confused reading of what is actually disclosed by the single cited and applied reference. Moreover, the Examiners' stated view and position of what the Ducharme *et al.* innovation is constitutes clear and convincing evidence that the Examiners have once more become lost in the verbiage of the cited and applied reference - which merely sets forth in words what is a conventional design and what are those commonplace features routinely shared by many different structural formats of intravenous needle-catheter assemblies generally.

C. Applicant, now again affirms and re-states his earlier-held position. Neither applicant nor his undersigned attorney have any desire or wish to engage in a needless and pointless quarrel with the Examiners concerning either the mode or manner by which they performed their instant evaluation. Such an argument would only create animosity and resentment; and there is no value or benefit in such things.

Thus, it remains applicant's true and sincere goal only to advance the prosecution of the present invention effectively. Accordingly, to achieve

applicant's true purpose, applicant and his undersigned attorney believe that, once again, a more carefully tailored recitation and a more particularly delineated wording of the essential elements comprising the present invention would be of far more benefit and value than engaging in mere argument. Via such additional specific amendment, applicant hopes to push forward and make substantive progress in the prosecution of the instant application.

II. The Elements Defining Applicant's Claimed Invention

Applicant's currently amended independent claims 9 and 10 respectively define his invention explicitly as an "improvement of an on-demand needle retaining and locking mechanism to prevent premature withdrawl of the piercing needle into a safety chamber". The instant invention is thus not only an unique structure for a an improved on-demand needle retaining and locking mechanism in a needle-catheter assembly; but also recites the intended purpose and function overtly as a mechanism to prevent premature withdrawl of the piercing needle into a safety chamber – *e.g.,* if a blood vessel was not successful cannulated on the first attempt. Accordingly, via this definition, the currently amended claims clearly point out and precisely set forth those structural elements, features and limitations and that readily distinguish and separate the instant invention

from all previously existing retaining and locking mechanisms.

It will be recognized that, as recited by claim 9, these unique elements are:

A needle-safety container which can be rotated radially on-demand, and has a sized solid tab member disposed at and extending radially from the open front end at an aligned position; and

A needle housing which is: (a) mounted over the needle-safety container and which is adapted for slidable axial movement and radial rotation movement at will over the needle-safety container, and (b) has a non-detachable hollow spool section permanently positioned at and joined to the front end of the needle housing for on-demand engagement with said solid tab member of said needle-safety container after said needle-safety container has been radially rotated.

It is also explicitly required by the language of independent claim 9 that the hollow spool section must comprise a central cavity, open front and rear ends adapted for passage there through by a piercing needle, a tab-engagement segment, and at least one notch within said tab engagement segment: wherein (i) the spool section is alignable at will with the solid tab member of said needle-safety container; (ii) the spool section can be engaged by and disengaged from the solid tab member of the rotable needle-safety container on-demand as a consequence of radially rotating the

needle-safety container; and (iii) the engagement of said spool section with said solid tab member of the radially rotated needle-safety container provides an on-demand needle retaining and locking mechanism.

In contrast, currently amended independent claim 10 is a substantive restatement of claim 9, but recites a slightly different and alternative definition of similar structural elements, limitations and features. The meaningful differences reside in the definition of the needle-safety container, which is now more particularly defined as being comprised of

(i) a non-rotable linear segment which is in an aligned axial orientation, and

(ii) a hollow collar segment which

(1) is attached to and aligned with the open front end of said non-rotable linear segment of the needle-safety container, and can be radially rotated at will independently from the non-rotable linear segment of the needle-safety container,

(2) presents at least one discrete wall of preset dimensions and configuration, and a central void space,

(3) has open front and rear ends adapted for passage there through of the tip of a piercing needle, and

(4) has a solid tab member disposed on and extending from the

discrete wall at a fixed position.

It will be appreciated that the definitions recited by currently amended independent claims 9 and 10 have been carefully tailored clearly state and explicitly point out where the solid tab member is located and positioned on the needle-safety container; specify where the hollow collar of claim 10 is positioned and what are its capabilities; and explicitly place a non-detachable spool section having unique structural components and functional capabilities at the front end of the needle housing. Applicant respectfully submits that it is these explicitly recited components which define, demonstrate and prove the novelty and distinctiveness of the improved on-demand needle retaining and locking mechanism constituting the present invention.

III. The Present Rejection Under 35 USC 102(b)

The Examiners have rejected the previously pending claims under 35 USC 102(b) as being anticipated by the Ducharme *et al.* '740 patent [U.S. Patent No. 5,591,138]. In explanation of this rejection, the Examiners have stated their views and position at Pages 2-3 of the Official Action.

In reply to this rejection, applicant believes it is initially useful to summarize what are the multiple legal obligations of the Examiners.

A. The Pertaining Legal Standards

Presentation Of A *Prima Facie* Case

The Examiners are legally obliged to present a *prima facie* case and to support factually each and every basis for rejection which is made. The requirement and burden of presenting a *prima facie* case is a procedural tool of patent application examination; and demands that facts or other probative evidence be shown to exist within the relevant prior art that would reasonably allow and support the conclusion that is the underlying rationale for rejection [see for example, *In re Piasecki*, 223 USPQ 785 (Fed. Cir. 1984) and the cases internally cited therein].

The Examiners can satisfy this requirement and legal burden only via an objective and specific showing that the prior art of record actually provides such information and knowledge; and also demonstrates that persons of ordinary skill in the pertinent art had public access to and awareness of such information and knowledge. Should the Examiners fail to present a *prima facie* case, there is neither adequate support or justification for any rejection basis as a matter of law.

Anticipation

As a matter of long established law, anticipation under 35 USC 102(b)

requires exact identity of the claimed article within a conventionally known device or apparatus existing previously in the prior art. Each required element or essential component of the claimed article of manufacture (including each specific feature and limitation defining the invention as a whole) must be described or embodied, directly or indirectly, within a single reference [Richardson v. Suzuki Motor Co., 9 USPQ2d 1913 (Fed. Cir. 1989)].

Moreover, the single prior art reference of record must describe the claimed subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art. Thus, the reference must describe applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field in possession of it [Akzo N.V. v. U.S. Int'l Trade Comm'n, 1 USPQ2d 1241 (Fed. Cir 1986)]; and that such prior existence of the claimed invention would be recognized by persons working in the field of the invention [In re Spada, 15 USPQ2d 1655 at 1657 (Fed. Cir. 1990)].

Also, in deciding the issue of anticipation, the Examiners must identify each requisite element and limitation recited within applicant's claims; determine their meaning in light of the description provided by the Specification; and identify the existence and presence for each of the corresponding elements and limitations within the disclosure of the allegedly anticipating reference [Scripts Clinical and Research Foundation vs.

Genetech Inc., 18 USPQ2d 1001 (Fed. Cir. 1991); Glaverbel Society Anonyme vs. Northlake Marketing and Supply Inc., 35 USPQ2d 1496 (Fed. Cir. 1995)].

Non-Obviousness

In addition, although not yet employed by the Examiners as a basis for rejection, it is deemed useful here also to identify the proper legal basis and standard for determining obviousness under 35 USC 103(a). Where applicant's claimed subject matter could be rejected as obvious in view of a single prior art reference (or a combination of two or more different references), a proper analysis must consider *inter alia* two factors: (I) whether the prior art of record would have suggested to those of ordinary skill in the art that they should make the claimed article; and (ii) whether the prior art would also have revealed that in so making, those of ordinary skill would have a reasonable expectation of success [In re Dow Chemical Company, 5 USPQ2d 1529 (Fed. Cir. 1988)]. Both the suggestion and the reasonable expectation of success must be found directly within the text of the prior art reference(s) itself and cannot be derived or extrapolated from applicant's disclosure [In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991)].

B. The Single Cited And Applied Reference Of Record:

The Examiners have employed the Ducharme *et al.* '740 patent [U.S. Patent No. 5,000,740] as the basis for the anticipation rejection. Applicant, however, respectively submits that the Examiners' views and conclusions as stated in the instant Official Action do not provide an adequate factual basis for rejection of the present invention - particularly as these remarks concern the invention defined by current amended independent claims 9 and 10 respectively. To the contrary, applicant submits and affirms that a proper and detailed review of the factual content actually disclosed by the single cited and applied prior art reference, the Ducharme *et al.* '740 patent, amply reveals the many substantive factual deficiencies and flaws in the Examiners' stated position. Such a factual review and summary is presented below.

C. The Factual Content Of The Ducharme et al. '740 Patent:

1. The Ducharme *et al.* invention is explicitly disclosed by the descriptive text of the '740 patent as being an improved intravascular needle assembly which covers the needle point after use to prevent accidental injury from used needles [Column 1, lines 4-7 and lines 18-34]. The improvement provided by the Ducharme *et al.* invention not only provides protection against accidental needle injury after the needle is withdrawn from the emplaced catheter, but also provides an intravenous catheter in a

smaller and smoother operating configuration which can be manipulated by small hands [Column 1, lines 53-57]. In preferred embodiments of the disclosed invention, a separate tip piece enables the mounting of a catheter hub over the needle guard tip; and a removable protective sheath is additionally provided to protect the catheter and needle of the intravascular needle assembly prior to its actual use [Column 2, lines 4-15 and lines 57-59].

2. As described by the figures and descriptive text of the '740 patent, the Ducharme *et al.* intravascular needle assembly (employed to cover the needle point after use in order to prevent accidental injury from used needles) must structurally comprise not less than four requisite and essential components [Column 1, lines 57-68 through Column 2, lines 1-3].

These are:

(i) A semi-tubular needle housing (reference numeral 20) that is open on the upper surface; is axially slidable; but cannot be radially rotated at any time [Column 3, lines 60-68 through Column 4, line 1].

(ii) A flash chamber (reference numeral 26) with a piercing needle (reference numeral 24) located within and extending beyond the distal end of the semi-tubular needle housing [Column 3, lines 45-59].

(iii) A tubular needle guard (reference numeral 30) which is axially slidable over the semi-tubular needle housing, but cannot be radially rotated at any time; has a bottom surface which is slotted to fit around the base of the flash chamber of the semi-tubular needle housing; is located for axial movement within the semi-tubular needle housing; and has a distal opening through which the piercing needle extends [Column 4, lines 10-33].

(iv) A locking mechanism which structurally appears at the rear of the bottom slot (reference numeral 36) of the tubular needle guard and which will engage and then interlock with the base of the flash chamber of the semi-tubular needle housing, but only after the tubular needle guard has been fully extended to cover the then withdrawn and retracted needle after its use [Column 3, lines 3-8; Column 4, lines 1-9; Column 5, lines 1-7].

3. In addition, as illustrated by the figures and specifically described by the text of the Ducharme et al. '740 patent, certain incidental structures and minor features are included and appear as part of the overall intravenous needle assembly. Representing these incidental structures and minor features are the following.

A first example, as shown by Figs. 1, 2, 3 and 4 respectively, are the contoured finger grips (reference numeral 22) molded on the sides of the semi-tubular needle housing [Column 2, lines 45-49]; and the small

projections (reference numeral 32) located on the upper surface of the tubular needle guard [Column 2, lines 51-54]. These finger grips and small projections are merely physical aids which permit the user to extend the tubular needle guard while holding the semi-tubular needle housing with one hand. They have no other purpose in the Ducharme *et al.* intravenous needle assembly.

A second example, as shown by Figs. 2, 3 and 4 respectively, is a push-off tab (reference numeral 34) which is present upon and projects upward from the distal end surface of the needle guard [Column 2, lines 64-66]. The sole purpose and intended function of this push-off tab as a structural feature is as a tangible aid during the retraction of the needle after use from a blood vessel into the interior of the needle guard as well as an aid in the subsequent threading of a catheter into the blood vessel [Column 5, lines 45-56]. No other purpose or functions exists for the existence of the push-off tab in the Ducharme *et al.* intravenous needle assembly.

A third example, as shown by Fig. 6c, is the presence of a flange (reference numeral 72) and of three ribs (reference numeral 86) appears as part of the needle housing structure and act solely to support the piercing needle at the distal end of the flash chamber. The flange is formed at the distal end of the housing; and the three ribs are formed uniformly around

the distal end of the flash chamber to afford more uniform material flow during the molding process [Column 3, lines 44-54]. No other purpose or functions exists for the existence of the flange and ribs in the Ducharme *et al.* intravenous needle assembly.

A fourth example, as shown by Figs. 9a and 9b, is the presence of a flange (reference numeral 44) which exists at the proximal end of a detachable protective sheath (reference numeral 40). The sheath is a discrete protective feature suitable for attachment to the distal end of the needle housing of the intravenous needle assembly prior to use; and the sheath body is of sufficient length to cover both the catheter and needle of the assembly prior to use. Structurally, the flange is nothing more than an extension of the sheath body appearing at the proximal end of the sheath, and the flange is formed and exists solely as an aid for better attachment of the sheath to the needle housing. Also, three projections (reference numeral 94) are formed and appear within the inner surface of the flange, and these inner projections function only to provide a more secure connection of the sheath body onto the needle housing of the intravenous needle assembly prior to use [Column 4, lines 34-51]. Neither the flange nor the three projections have any other purpose or function within the Ducharme *et al.* intravenous needle assembly.

4. The structure of the locking mechanism by which the piercing needle can be moved from a retracted position and locked into a permanently covered position is best illustrated by Fig. 11 and is specifically described by the Ducharme *et al.* '740 patent text [Column 1, lines 64 -68 through Column 2, lines 1-3; Column 3, lines 3-8; and Column 5, lines 59-68].

As stated therein, after the needle of the assembly has pierced the blood vessel and the needle has been withdrawn and retracted out of the blood vessel, the tubular needle guard is extended to cover the retracted needle. As the tubular needle guard is fully extended for this purpose, the narrowed proximal end (reference numeral 92) of the bottom slot of the needle guard will become spread by the base of the flash chamber of the needle housing; and such spreading continues until the narrowed slot portion engages an aperture (reference numeral 74), which will hold the flash chamber base and permanently lock the tubular needle guard in the extended and needle protective position [Column 5, lines 59-68].

5. One other fact also stands out clearly as regards the Ducharme *et al.* locking mechanism: After the needle has been retracted and the tubular needle guard has been extended to cover the retracted needle, the extended

covering position of the tubular needle guard then becomes permanently locked in place by the mechanism. Thus, once the tubular needle guard is locked into the covering position, the tubular needle guard must remain in the fully extended covering position forever. There is no structural release mechanism nor any unlocking procedure disclosed by the Ducharme *et al.* '740 patent text; and there is no capability whatsoever to adjust or modify the Ducharme *et al.* locking mechanism in order to release the extended tubular needle guard after the locking mechanism has been engaged.

6. Accordingly, as clearly described and illustrated by the Ducharme *et al.* '740 patent, the following facts are unequivocally demonstrated to be true:

(i) The structure of the locking mechanism physically exists and appears only at the proximal end of the tubular needle guard;

(ii) The structure of the locking mechanism existing at the proximal end of the tubular needle guard becomes engaged and interlocked with the needle housing only after the tubular needle guard has been fully and completely extended;

(iii) The engagement of the locking mechanism and interlocking event with the needle housing can occur only after the

piercing needle has been entirely retracted and is located entirely inside of the tubular needle guard;

(iv) There is no capability whatsoever to adjust or modify the Ducharme *et al.* locking mechanism in order to release the extended tubular needle guard after the locking mechanism has been engaged; and

(v) The sole purpose and value of the Ducharme *et al.* locking mechanism is to provide some protection for the user of the intravenous needle assembly against accidental needle injury after the needle has been withdrawn from the emplaced catheter

This factual summary accurately presents the sum and substance of the information actually disclosed by the Ducharme *et al.* '740 patent.

D. The Major Differences Existing Between Applicant's Claimed Invention And The Ducharme et al. '740 Patent:

Applicant respectfully submits and maintains that there are many major differences and marked distinctions between the instant invention defined by the presently amended claims and the subject matter disclosed

by the Ducharme *et al.* '740 patent reference. Among them are the following:

1. The Ducharme *et al.* invention is an improved intravascular needle assembly which covers the needle point after use to prevent accidental injury from used needles. In contrast, applicant's claimed invention is an improved on-demand needle retaining and locking mechanism which prevents premature withdrawl of the piercing needle into a safety chamber – *e.g.,* if a blood vessel was not successful cannulated on the first attempt. Clearly, each structure is directed to an entirely different and unrelated purpose and function.

2. The Ducharme *et al.* invention requires a semi-tubular needle housing that is open on the upper surface, is axially slidable, but cannot be radially rotated at any time; and a tubular needle guard which is axially slidable over the semi-tubular needle housing, but cannot be radially rotated at any time. Distinctively, applicants claimed invention demands a needle-safety container which can be rotated radially on-demand; and a needle housing which is mounted over the needle-safety container and which is adapted for slidable axial movement and radial rotation movement at will over the needle-safety container.

3. The Ducharme *et al.* invention makes no requirement or demand for: (i) a non-detachable hollow spool section permanently positioned at and joined to the front end of the needle housing for on-demand engagement with said solid tab member of said needle-safety container after said needle-safety container has been radially rotated; and (ii) a hollow spool section which comprises a central cavity, open front and rear ends adapted for passage there through by a piercing needle, a tab-engagement segment, and at least one notch within said tab engagement segment. In fact, there is no information of any kind within the Ducharme *et al* '740 patent text that even hints, much less implies, the existence of any of these structural elements and features demanded by applicant's claimed invention.

4. The Ducharme *et al.* invention requires a locking mechanism which is located at the proximal ends of the needle housing and the tubular needle guard. In comparison, applicant's needle retaining and locking mechanism is located at the front of the needle-safety container and the needle housing.

5. The Ducharme *et al.* invention requires a locking mechanism which structurally exists at the rear of the bottom slot in the tubular needle guard and which will engage and then interlock with the base of the flash chamber of the semi-tubular needle housing, but only after the tubular needle guard

has been fully extended to cover the then withdrawn and retracted needle after its use.

In contrast, the present invention makes no such demands whatsoever. Applicant's on-demand needle retaining and locking mechanism does not require any guide slots configured to receive any projection, and does not require movement of the needle-safety container forward into an extended needle covering position. Instead, applicant's invention requires the engagement of a spool section with a solid tab member to provide the on-demand needle retaining and locking mechanism.

6. The Ducharme *et al.* invention requires that, once the tubular needle guard is locked into the covering position, the tubular needle guard must remain in the fully extended covering position forever. There is no structural release mechanism, nor any unlocking procedure disclosed by the Ducharme *et al.* '740 patent text; and there is no capability whatsoever to adjust or modify the Ducharme *et al.* locking mechanism in order to release the fully extended tubular needle guard after the locking mechanism has been engaged.

In major contradistinction, applicant's needle retaining and locking mechanism is structurally and functionally capable of being engaged and

disengaged repeatedly and on-demand. There is no permanent locking in place limitation imposed on applicant's invention; and the required structural elements comprising the needle retaining and locking mechanism are purposefully defined to provide the specific capability of being engaged and disengaged repeatedly at will.

D. The Examiners' Stated Reasons And Rational For Rejection Are Flawed And Inaccurate:

Also as a consequence of the factual review of the Ducharme et al. '740 patent presented above, and its comparison with the currently claims of the instant invention, applicant respectfully affirms that the stated reasons and rationale for rejection given by the Examiners at pages 2-3 of the instant Official Action are factually inaccurate and without evidentiary support. Applicant respectfully directs attention to the following instances where the Examiners' statements are substantively flawed and inaccurate.

1. The Examiners have stated that the Ducharme *et al.* '740 patent discloses "...a needle safety container 22 which is radially rotable by hand on-demand...". However, this is a completely erroneous statement, as the factual summary presented above shows.

Clearly, there is only a semi-tubular needle housing (reference numeral 20) in the Ducharme *et al.* assembly. This housing is open on the upper surface; is axially slidable; but cannot be radially rotated at any time [Column 3, lines 60-68 through Column 4, line 1 of the reference].

Similarly, there is only a tubular needle guard (reference numeral 30) in the Ducharme *et al.* assembly. It is axially slidable over the semi-tubular needle housing, but cannot be radially rotated at any time. Also, it must have a bottom surface which is slotted to fit around the base of the flash chamber of the semi-tubular needle housing; is located for axial movement within the semi-tubular needle housing; and has a distal opening through which the piercing needle extends [Column 4, lines 10-33 of the reference].

2. The Examiners have stated that the Ducharme *et al.* '740 patent discloses "...a sized solid tab member 34 disposed at and extending radially from said open front end at an aligned position...". On this point, however, the Examiners have clearly ignored and overlooked the undisputed fact that the push-off tab (reference numeral 34) present upon and projecting upward from the distal end surface of the Ducharme *et al.* needle guard bears no relationship to applicant's sized solid tab member [see Column 2, lines 64-66 of the reference].

Apparently the Examiners have refused to recognize or admit that the sole purpose and intended function of this Ducharme *et al.* push-off tab - as a structural feature - is only as a tangible aid during the retraction of the needle after use from a blood vessel into the interior of the needle guard; and merely as an aid in the subsequent threading of a catheter into the blood vessel [see Column 5, lines 45-56 of the reference]. No other purpose or functions exists for the existence of the push-off tab in the Ducharme *et al.* intravenous needle assembly. Thus, the Examiners' rationale is flawed and without any foundation.

3. The Examiners have also stated that the Ducharme *et al.* '740 patent discloses "...a slideable hollow configured spool [Fig 9B] joined to the front end of the needle housing for on-demand engagement with said solid tab member of said needle-safety container..". This statement is a gross exaggeration and complete misrepresentation of what the Ducharme *et al.* text actually discloses.

What is truly shown by Figs. 9a and 9b in the Ducharme *et al.* patent is the presence of a detachable protective sheath (reference numeral 40) which has a discernible flange (reference numeral 44) existing of part of the sheath construction at its proximal end, as explicitly described at Column 4, lines 34-51 of the text. The sheath is a discrete protective feature suitable

for attachment to the distal end of the needle housing of the Ducharme *et al.* intravenous needle assembly prior to use; and the sheath body is of sufficient length to cover both the catheter and needle of that needle assembly. Structurally however, the flange is nothing more than an extension of the sheath body appearing at the proximal end of the sheath, and the flange is formed and exists solely as an aid for better attachment of the sheath to the needle housing.

Also, three discrete projections (reference numeral 94) also appear within the inner surface of the flange; and these inner projections function only to provide a more secure connection of the sheath body onto the needle housing of the intravenous needle assembly prior to use [see Column 4, lines 44 -51 of the reference].

Clearly however, neither the flange nor the three projections have any other purpose or function within the Ducharme *et al.* intravenous needle assembly – other than what is factually described by the '740 text. The Examiners' re-casting of this limited quantity and quality of information to be a "a slideable hollow configured spool" is thus a gross distortion, exaggeration, and misrepresentation of what is truly disclosed by the Ducharme *et al.* patent.

4. The Examiners have stated that the Ducharme *et al.* '740 patent discloses a "...hollow configured spool section comprising a central cavity [NEAR 48], open front and rear ends adapted for passage there through by a piercing needle, a flanged rib 86, a tab-engagement segment 42, and at least one notch within said tab engagement section 94...". The Examiners' statements are notably flawed and inaccurate.

An objective reading of the '740 patent text reveals that there is no configured spool section as such disclosed at all by the Ducharme *et al.* '740 patent. Instead, the Examiners have irrationally combined portions of the detachable protective sheath explicitly described at Column 4, lines 34-51 of the patent text with certain incidental structures and minor features which are included and appear as part of the overall Ducharme *et al.* intravenous needle assembly.

Note in particular that that the alleged "tab engagement section 42" stipulated by the Examiners is in actual fact merely -- a release tab 42 used to release the sheath from the catheter assembly prior to use of the catheter -- [see Column 4, lines 41-42 of the Ducharme *et al.* '740 patent text]. A sheath has no bearing with or relationship of any kind to a configured spool section, structurally or functionally. The Examiners' presentation of and reliance upon such a coarse distortion and mis-statement of fact is thus gross and blatant error.

The Examiners have also wrongly emphasized and grossly distorted the true meaning and value of the flange (reference numeral 72) and of three ribs (reference numeral 86) – both of which appear as part of the needle housing structure and act solely to support the piercing needle at the distal end of the flash chamber in the Ducharme *et al.* patent disclosure. Note that the flange is formed at the distal end of the housing; and the three ribs are formed uniformly around the distal end of the flash chamber to afford more uniform material flow during the molding process [see Column 3, lines 44-54 of the reference]. No other purpose or functions exists for the existence of the flange and ribs in the Ducharme *et al.* intravenous needle assembly. This is merely once more instance of the Examiners' continuing gross and blatant errors.

5. The Examiners have completely mis-stated and misconstrued what the applicant's improvement of an on-demand needle retaining and locking mechanism actually is - to prevent premature withdrawl of the piercing needle into a safety chamber if a blood vessel was not cannulated successfully on the first attempt; and instead mis-focused and confused the present invention into something which it is not – a locking mechanism used to provide some protection for the user of the intravenous needle assembly against accidental needle injury after the needle has been withdrawn from

the emplaced catheter.

6. Furthermore, as clearly described and revealed by the Ducharme *et al.* '740 patent text, the following facts directly oppose and contradict the Examiners' stated reasons and rationale for rejection.

(a) The structure of the Ducharme *et al.* locking mechanism physically exists and appears only at the proximal end of the tubular needle guard;

(b) The structure of the Ducharme *et al.* locking mechanism existing at the proximal end of the tubular needle guard becomes engaged and interlocked with the needle housing only after the tubular needle guard has been fully and completely extended; and

(c) The engagement of the Ducharme *et al.* locking mechanism and interlocking event with the needle housing can occur only after the piercing needle has been entirely retracted and is located entirely inside of the tubular needle guard;

(d) There is no capability whatsoever to adjust or modify the Ducharme *et al.* locking mechanism in order to release the extended tubular needle guard after the locking mechanism has been engaged; and

(e) The sole purpose and value of the Ducharme *et al.* locking mechanism is to provide some protection for the user of the intravenous needle assembly against accidental needle injury after the needle has been withdrawn from the emplaced catheter

7. Applicant submits that the Examiners' unfortunate mode and manner of again attempting to substantiate and support their views by referring merely to certain figures within the Ducharme et al. '740 patent, is factually inadequate as well as legally improper and impermissible

The Examiners are overtly and legally obliged to show that each required element or essential component of applicant's claimed article of manufacture exists in the prior art; and this obligation demands that each specific element, limitation and feature of applicant's claimed invention as a whole must be clearly identified, described or embodied within a single cited reference of record.

Applicants maintains that the Examiners' evaluation technique (as demonstrated in the instant Official Action) does not support their views with specific facts or direct evidence from the prior art reference - but instead points only vaguely and elusively to certain figures in the cited reference. This mode of explanation is neither demonstrative nor illustrative of relevant facts; and does not identify applicant's claimed subject matter with sufficient

clarity or adequate detail to establish that the claimed subject matter existed in fact within the prior art. The Examiners thus did not perform their legal duty properly.

IV. Applicant's Position and Conclusions

1. Applicant respectfully submits that the Examiners have not properly recognized the limited informational content of, and have not appreciated the particular structural requirements for, the locking mechanism disclosed by the Ducharme *et al.* '740 patent; and have unfortunately overlooked the constrained value of the Ducharme *et al.* operational mechanism which covers the needle point after use to prevent accidental injury from used needles, as is explicitly taught by the cited reference of record.

2. Applicants also maintain that the Examiners have unfortunately wrongly chosen to extrapolate only certain items and to over-emphasize the value of specified details from the totality of information disclosed by the Ducharme et al. '740 patent; and have misapplied the true value of these extrapolated items, particularly as regards the structure and function of incidental structures and minor features existing within the Ducharme et al intravenous needle assembly.

3. Applicant further submits and maintains that a discrete spool section joined to the front end of the needle housing for on-demand engagement with the solid tab member of a rotable collar - in which the configured spool section comprises a central cavity, open front and rear ends adapted for passage there through by a piercing needle, a tab-engagement segment, and at least one notch disposed within the tab engagement segment - is radically different and completely unrelated in structure and operation to the Ducharme *et al.* locking mechanism, which exists only at the proximal end of the tubular needle guard and which becomes engaged and interlocked with the needle housing only after the tubular needle guard has been fully and completely extended a retracted piercing needle. No amount of subjective distortion can convert such a proximal-end located locking mechanism disclosed by the Ducharme *et al.* '740 patent into a frontally located configured spool section as required by applicant's claims.

Applicant therefore affirms that the information content and value disclosed and/or implied by the Ducharme *et al.* '740 patent of record does not teach or suggest applicant's claimed subject matter with sufficient clarity or detail to establish that the instant invention existed in the prior art; and overtly denies that the present invention could or would be recognized by persons of ordinary skill in the art, given full knowledge and awareness of

the Ducharme *et al.* '740 patent.

Equally important, applicant also maintains that the Ducharme *et al.* '740 patent of record cannot suggest to those of ordinary skill in the relevant technical field that they should make applicant's claimed apparatus or utilize applicant's claimed invention for its intended purposes; nor does the '740 patent text reveal or imply that, if one attempted to make or practice applicant's presently claimed invention, those of ordinary skill would have any reasonable expectation for success.

For all these reasons, applicant therefore respectfully submits that each and every amended claim now pending satisfies the novelty requirements of 35 USC 102(b), as well as the non-obvious requirement of 35 USC 103(a). Accordingly, applicant respectfully requests that the Examiners reconsider their stated position and withdraw this ground of rejection against the currently pending claims.

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In sum, applicant has directly and forthrightly addressed the single basis of rejection stated in the most recently received (non-final) Official Action. In applicant's view, the single issue has been addressed and resolved completely. For these reasons, applicant respectfully submits and affirms that each of currently pending claims 6 and 9-10 are therefore allowable

In view of the above discussion and detailed review, applicant believes that this application is now in condition for allowance and reconsideration is respectfully requested. The Examiners are invited to call applicant's undersigned attorney should they feel that such a telephone call would further the prosecution of the present application.

Respectfully submitted,

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